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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,494	07/02/2007	Rainer Pommersheim	1374-3 PCT/US	8350

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EXAMINER	
POURBOHLOUL, SARIRA CAMILLA	
ART UNIT	PAPER NUMBER
1796	
MAIL DATE	DELIVERY MODE
02/04/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,494	POMMERSHEIM, RAINER	
	Examiner	Art Unit	
	S. CAMILLA POURBOHLOUL	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-31 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 09/21/2006.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim interpretation

The claims 1 and 17 contain phrases “preferably an envelope” and “may be surrounded by” which imply that the claims do not require an envelope or do not have to be surrounded by a multilayered envelope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Pommersheim (US 2003/0129248).

Regarding claims 1, 6-9, and 16, Pommersheim discloses a microcapsule comprising a solid spherical [0015] core containing immobilized solid material as well as liquid, gases, living cells and bacterial cells, surrounded by a multilayered membrane [0014], wherein the microcapsules can be stably stored in a concentrated medium and upon dilution the membrane is destroyed [0009] [0031]. The encapsulated material is completely enclosed by the matrix core [0001] [0019] and the core is surrounded by a multilayer membrane (i.e. envelope) ([0016]; claim 4). The membrane layers can be

applied by electrostatically bonding the membrane material to the adjacent layer [0016] and/or by coating the core with a solid or a liquid [0017].

Regarding claim 2-5, Pommersheim discloses that the core consists of a base material from which a matrix is formed in which the encapsulated substance is embedded. This base material is capable of being dispensed as droplets and/or emulsified from which by means of precipitation under the action of ions or a temperature gradient preferably spherical particles can be formed [0015]. Furthermore, the substance surrounding the encapsulated, immobilized material is a low-viscosity oil or a volatile hydrocarbon and the material to be immobilized forms a suspension [0014] [0023] or a liquid/liquid emulsion ([0014]; claim 15).

Regarding claim 10-14, Pommersheim discloses that its microcapsule acquire its coated membrane through a fluidized-bed process [0024] during which microcapsules can be coated with solid particles and subsequently dried [0026]. The microcapsules retain their functionality following drying [0011]. Moreover, if the microcapsules are to be employed in the food or pharmaceutical area, the components of the microcapsule are chosen from the food-approved group such as sugar, milk powder, shellac, alginate or other permitted substance [0017].

Regarding claim 15, Pommersheim discloses that the microcapsule core is constructed as follows: the substance to be immobilized is suspended or dissolved by a liquid called base material which is immiscible with the matrix material [0015] [0023]. This base material must be a substance capable of being dispensed as droplets and/or emulsified, from which by means of precipitation under the action of ions or a

temperature gradient preferably spherical particles can be formed. Such substances include, for instance, sodium alginate but also agarose or Sephadex as well as paraffins or ceramics etc [0015]. Following precipitation the drops can be sealed with a membrane. This membrane can consist of a polyelectrolyte complex, which can be applied in multiple layers. Polyelectrolyte complexes of this kind are formed by the interaction of a polyanion and polycation. As the polyanion, water-soluble cellulose derivatives such as carboxymethyl cellulose, cellulose sulfate or pectins, alginates as well as synthetic polymers such as polyacrylic or polymethacrylic acids and the like are advantageously employed. Chief among the polycations to be considered are natural substances such as chitosan, but also synthetic polymers such as polyethylene imine or polydiethyl diallyl ammonium chloride [0016]. However, a membrane on the capsule surface can also be produced by drying. This can be done in two ways. Either the capsules are incompletely dried, for instance with relatively hot air, so that a crust forms on its surface, or other substances are blown into the dryer along with the drying air. These preferably solid or liquid substances become firmly attached to the capsule surface and thus form a membrane; this situation is referred to as "coating" [0017].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pommersheim as applied to claims 1-16, in view of Wheatley et al. (US 4,933,185).

Although, Pommersheim teaches enzymes being part of the core material [0031], it does not teach the core enzyme being capable of breaking down substances in the capsule matrix or membrane. Pommersheim discloses that sodium alginate is chosen as the matrix material and it gels by precipitation in a solution of polyvalent metal ion. This gleation can be reversed by exposing the capsule to sodium citrate solution [0021]. Furthermore, Pommersheim teaches that the capsule is destroyed and the core substance released when its imposed load reaches a particular level and the capsule core can be destroyed after the coveing has been applied, in an additional procedural step that makes it fluid again [0021]. Pommersheim does not include an enzyme in the core matrix that will assist in the destruction of the matrix or shell. In the same field of endeavor, Wheatley et al. teaches a system for controlled-release of biologically-active substances by microencapsulating the active substance along with an enzyme capable of degrading a core substance (col. 2, lines 66-col. 3, lines 1-5), wherein the activation

of the enzyme leads to breakdown of the core substrate and slow release of the active material from the capsule (col. 3, lines 42-59). The enzyme is selected according to the type of the core substance used. For instance, alginate core requires alginase enzyme and pectin core requires a pectinase enzyme (col. 5, lines 4-15; claim 5). Wheatley discloses a controlled release of a biologically active substance with an enzyme degrading core. Therefore, it would have been obvious to include the enzyme of Wheatley in the Pommersheim core in order to controllably release the biologically active agent instead of a rapid release of the active agent which would happen under Pommersheim's method lacking the enzyme.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. CAMILLA POURBOHLOUL whose telephone number is (571)270-7744. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James J. Seidleck/
Supervisory Patent Examiner, Art Unit 1796

/SCP/